UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ZOLOFT (SERTRALINE HYDROCHLORIDE) PRODUCTS LIABILITY LITIGATION	§	**MDL NO. 2342**
	§	
	§	**12-MD-2342**
	§	
THIS DOCUMENT RELATES TO: ALL ACTIONS	§	**HON. CYNTHIA M. RUFE**
	§	

DEFENDANTS' MEMORANDUM IN SUPPORT OF THEIR MOTION TO DE-DESIGNATE DOCUMENTS MARKED AS CONFIDENTIAL BY PLAINTIFFS REGARDING THEIR COMMUNICATIONS WITH STUDY AUTHORS

TABLE OF CONTENTS

Page

PRELIMINARY STATEMENT 1

BACKGROUND 3

A. Plaintiffs' Request for Documents 4

B. Pfizer's Request for Documents 4

C. Plaintiffs' Subpoenas for Documents Directed to Louik (2007) Study Authors 5

D. The Facts Revealed in the Recently-Produced Documents Are Notable 5

1. Documents Pertaining to Whether the Zoloft Findings in Bérard (2015) Are Not Statistically Significant 5

2. Documents Regarding the Now-Published Correction to Louik (2007) 8

3. Documents Regarding Dr. Jewell's Re-Analysis of Huybrechts (2014) 13

I. THE COURT SHOULD ORDER PLAINTIFFS TO DE-DESIGNATE THE DOCUMENTS AS CONFIDENTIAL 15

CONCLUSION 15

TABLE OF AUTHORITIES

Page

Cases

Daubert v. Merrell Dow Pharms., Inc.,
509 U.S. 579 (1993) .....passim

Matrixx Initiatives, Inc. v. Siracusano,
131 U.S. 1309 (2011).....10, 12

Shingara v. Skiles,
420 F.3d 301 (3d Cir. 2005).....15

In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig. (Zoloft I),
26 F. Supp. 3d 449 (E.D. Pa. 2014).....10

In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig. (Zoloft III),
2015 WL 314149 (E.D. Pa. Jan. 23, 2015).....10

Secondary Sources

Bérard et al., *Sertraline Use During Pregnancy and the Risk of Major Malformations*,
Am. J. Obstet. Gynecol. (2015), doi 10.1016/j.ajog.2015.01.034.....2, 5-8

Huybrechts et al., *Antidepressant Use in Pregnancy and the Risk of Cardiac Defects*,
370 NEJM 2397 (2014).....2, 13-15

Louik et al., *First-Trimester Use of Selective Serotonin-Reuptake Inhibitors and the Risk of Birth Defects*, 356 NEJM 2675 (2007).....3, 5, 8-10, 12-13

Reefhuis et al., *Specific SSRIs and birth defects: bayesian analysis to interpret new data in the context of previous reports*, BMJ 350:h3190 (2015).....10, 12

Rothman, et al., *Modern Epidemiology* (3d ed. 2008).....10

PRELIMINARY STATEMENT

This Court postponed the *Daubert* hearing over the admissibility of Nicholas Jewell, Ph.D.'s general causation opinion, among other reasons, to allow for certain discovery to take place. Plaintiffs asked, for example, that the *Daubert* hearing be adjourned to give them the opportunity to conduct certain discovery on communications between authors of birth defect studies and Pfizer's counsel and experts. After the hearing was adjourned, Pfizer timely produced the documents sought by Plaintiffs. Pfizer, in turn, served the same discovery request on Plaintiffs, seeking communications between study authors and Plaintiffs' counsel and experts.

While the Plaintiffs' Steering Committee (PSC) has produced the requested documents, they have unjustifiably designated some of those documents (Ex. 1, [redacted]) as "confidential" and "subject to the Protective Order" in this case. There is no legitimate basis for Plaintiffs' confidentiality designations. The documents do not reveal any "individually identifiable health information" under the Health Insurance Portability and Accountability Act of 1996 and 45 C.F.R. § 160.103 (HIPAA), or "Plaintiff's personal identifying information, financial information, and medical/insurance information." PTO 8 ¶ 1.

While the documents produced by the PSC reveal facts that Plaintiffs may not wish to divulge publicly, they are not confidential. Just as they did when trying to shield Dr. Jewell's Prozac report and deposition from discovery, which expose his situational science in tailoring his opinions to meet the demands of his assignment in a given case, Plaintiffs are now making unfounded confidentiality designations to conceal the truth about matters that bear upon this Court's *Daubert* analysis and upon vital issues concerning the public health.

Review of these documents reveals why Plaintiffs have designated them as confidential and are trying to keep them out of public view. The documents destroy whatever slender reed might have been left of the scientific basis of their case. The documents also raise serious questions as to candor in proceedings governed by this Court. But those are not the standards for designating documents as confidential. Nor is the purpose of the Protective Order to allow litigants to keep damaging documents out of the public eye. There must be a protectable legal

interest. There is none here.

The documents that have been produced uncover several important facts that bear directly on this Court's *Daubert* inquiry. For example, the documents reveal [redacted]

The documents also expose the hypocrisy in Plaintiffs' counsel's feigned outrage that communications by Pfizer's counsel and experts with study authors were somehow improper "ex parte" contacts. They were not. Yet, at the July 7, 2015 hearing, as Plaintiffs were questioning the propriety of the communication by Pfizer's counsel and expert with study authors, Plaintiffs knew – as the emails establish – that Plaintiffs' counsel and Dr. Jewell had communicated with study authors, including [redacted] the day of the hearing.

[redacted]

On July 7, 2015 – the same day Plaintiffs were decrying so-called "ex parte" communications – Dr. Jewell emailed Allen Mitchell, Ph.D., the senior author of Louik (2007). Dr. Jewell asked about Dr. Mitchell's communications with Dr. Kimmel. Dr. Mitchell replied that "Dr. Kimmel brought to our attention a potential error in one of our confidence bounds that we published in the NEJM. There was indeed an error, and we have submitted a correction to the Journal." Ex. 10 at 47. This substantive correction to Louik (2007), which is now formalized and published, presents a real problem for Plaintiffs: there are no replicated, consistent findings of a statistically significant association between Zoloft and septal defects.

Since the *Daubert* hearing, Plaintiffs' counsel and their experts, including consulting expert Sander Greenland, Ph.D., have continued to contact study authors, in what appears to at least raise serious questions concerning Plaintiffs' attempts to influence the scientific literature.

In short, and as explained in detail below, these and other documents are directly relevant to Pfizer's *Daubert* motion and there is no legitimate basis for Plaintiffs' blanket confidentiality designations. The Court should order Plaintiffs to de-designate these documents.

BACKGROUND

On July 7, 2015, the *Daubert* hearing to assess the admissibility of Dr. Jewell's testimony was scheduled to commence. Before opening statements, Plaintiffs urged the Court to postpone the hearing. Plaintiffs argued that adjourning the hearing was necessary because they needed additional time to seek discovery into communications between Pfizer's experts and study authors. 7/7/15 Hr'g Tr. at 11:6-24. In so arguing, Plaintiffs suggested that there was something untoward and improper about such communications, labeling them as "ex parte hearsay." *Id.* at 21:1-7. Plaintiffs then amplified this theme in their "emergency" motion for expedited discovery, filed on July 13, 2015, repeatedly characterizing the communications as "ex parte" and an "effort to undermine Plaintiffs' experts' opinions." Pls' Mot. [1438] at 1-4.

But Plaintiffs had known for months that Pfizer's expert, Dr. Kimmel, and counsel had contacted study authors. Yet Plaintiffs never followed up with any discovery requests and they

affirmatively waived their right to depose Dr. Kimmel. Instead, they waited until the day of the *Daubert* hearing to raise the issue. Moreover, as Plaintiffs' document production reveals, [redacted]

A. Plaintiffs' Request for Documents

On July 9, 2015, the PSC requested Pfizer to produce documents between study authors and Pfizer's counsel and experts. *E.g.*, Pls' RFP [1438-1] at 9 (Request No. 4). Plaintiffs' document request unilaterally set a shortened deadline of July 20, 2015. On July 13, 2015, seven days before the already shortened deadline set by Plaintiffs, Plaintiffs filed an "emergency" motion to compel. Pls' Mot. [1438] at 1. As Pfizer explained in its response, Plaintiffs' motion was premature and unnecessary. Pfizer's Resp. [1445] at 1. If Plaintiffs had asked, they would have learned that Pfizer was prepared to produce the documents between its attorneys and experts with study authors by Plaintiffs' self-imposed deadline. Pfizer timely produced the requested documents on July 20, 2015. *See generally* Pfizer's 7/20/15 Doc. Prod. Pfizer did ***not*** designate any of the documents as confidential or subject to the Protective Order in this case.

B. Pfizer's Request for Documents

On July 14, 2015, Pfizer served a document request on Plaintiffs that mirrored Plaintiffs' request. Pfizer requested Plaintiffs to produce communications between study authors and Plaintiffs' counsel and experts. Pfizer's RFP at 5 (Ex. 2). On August 1, 2015, Plaintiffs responded to Pfizer's request. Unlike Pfizer, Plaintiffs designated their initial production, in its entirety, as confidential and subject to the Protective Order. Pfizer has twice asked Plaintiffs to de-designate the documents, but despite these requests they have not done so.[1]

On August 6 and 7, 2015, the PSC supplemented their production. *See* Pls' 8/6/15 Supp'l Prod. (Ex. 5); Pls' 8/7/15 Supp'l Prod. (Ex. 6). Plaintiffs did ***not*** designate any of these newly-produced documents – which include emails between study authors and Plaintiffs' expert that

[1] *See* emails from M. Cheffo to M. Robinson, 8/2/15 (Ex. 3) & 8/7/15 (Ex. 4).

pre-dated their August 1 production – as confidential and subject to the Protective Order.

C. Plaintiffs' Subpoenas for Documents Directed to Louik (2007) Study Authors

On or about July 16, 2015, Plaintiffs served subpoenas upon Drs. Louik and Mitchell, two of the co-authors of Louik (2007). Pls' Louik Subpoena (Ex. 7); Pls' Mitchell Subpoena (Ex. 8). In those subpoenas, Plaintiffs sought documents from these study authors regarding their corrections to Louik (2007). On August 6, 2015, Drs. Louik and Mitchell complied and produced documents responsive to the subpoenas (Exs. 9 & 10).[2] None of the documents, which include communications between the Louik (2007) study authors and Plaintiffs' experts, is designated as confidential or subject to the Protective Order.

D. The Facts Revealed in the Recently-Produced Documents Are Notable

This recent discovery, much of which the PSC has designated as confidential and subject to this Court's Protective Order, reveals many facts that are relevant not only to this Court's *Daubert* analysis, but also to issues of public health. Some of the highlights are presented below.

1. Documents Pertaining to Whether the Zoloft Findings in Bérard (2015) Are Not Statistically Significant

In his report, Dr. Jewell cites the Bérard (2015) study, including Dr. Berard's purported "significant finding for 'Ventricular/atrial septal defect': OR: 1.34 (1.02-1.76)."[3] Jewell Rpt. [1210-9] at 25. As Pfizer explained in its *Daubert* briefing (*see* Pfizer's Br. [1210-1] at 29), Dr. Kimmel identified potential errors in Bérard (2015), including her supposedly statistically significant finding for atrial/ventricular septal defects. Kimmel 3/27/15 Rpt. at 14-16 (Ex. 11). As Dr. Kimmel writes, there is an "overarching, major concern, that makes the results" of Bérard (2015) "totally unreliable at this time." *Id.* at 15. The problem is that the "confidence intervals (and thus the statistical significance) for the only two statistically significant findings are not consistent with any of the other analyses, nor with what would be expected from the data." *Id.*

[2] For ease of reference, Pfizer has added page numbers to these exhibits. No alterations to the substance of the documents have been made.

[3] Bérard et al., *Sertraline Use During Pregnancy and the Risk of Major Malformations*, Am. J. Obstet. Gynecol. (2015), doi 10.1016/j.ajog.2015.01.034 [1210-49].

Using open source epidemiology software, and based on the unadjusted data in Bérard (2015), Dr. Kimmel examined the confidence intervals for ***all*** thirteen of the Zoloft findings in Table 2 of Bérard (2015) and was able to confirm all of them, ***except*** for the two that she reported as statistically significant (ventricular/atrial septal defects and craniosynostosis). *Id.* More particularly, in assessing the crude data in Table 2, Dr. Kimmel calculated the 95% confidence intervals for ventricular/atrial septal defects as non-statistically significant (0.69-2.65) in contrast to the (1.01-1.79) reported in Bérard (2015). Likewise, for craniosynostosis, (0.61-6.21) versus the (0.99-3.81) reported in Bérard (2015). *Id* at 16. Thus, Dr. Kimmel states that "[u]ntil these discrepancies can be resolved, the findings of this paper must be deemed unreliable." *Id.*

After noting that [redacted], Plaintiffs' August 1 document production – which they seek to keep hidden behind this Court's Protective Order – reveals that [redacted].

At the *Frye* hearing held in Pennsylvania on February 13, 2015, Pfizer cross-examined Dr. Jewell about Bérard (2015) and whether any of the Zoloft findings are actually statistically significant. [redacted] Dr. Kimmel's analysis of Bérard (2015). [redacted] Dr. Kimmel's calculations. [redacted]

[redacted] Dr. Jewell was deposed by Pfizer on May 5, 2015. Upon being directly asked, Dr. Jewell ***denied*** that he independently assessed Dr. Bérard's data: "no, I did not independently assess her data." Jewell 5/5/15 Dep. (Ex. 12) at 258:3-17. Dr. Jewell further testified that one could ***not*** double-check Dr. Bérard's confidence intervals using the crude data presented in Table 2 of her study. *Id.* at 260:25-261:13. [redacted] His sworn deposition testimony taken in this case – that as to the crude data "you don't have enough information probably to get the confidence intervals from the paper" (Jewell 5/5/15 Dep. (Ex. 12) at 261:8-13), and he ***cannot*** tell "whether what [Dr. Bérard] did is still right or wrong" (*id.* at 263:10-264:1) [redacted].

Whether Bérard (2015) has inaccurately reported data is relevant to this Court's *Daubert* analysis. Documents addressing that issue should not be withheld from public view. This is

particularly true of documents that reveal that [redacted] The public, including the medical and scientific community, deserve to know the truth. Just as a correction was recently published to Louik (2007) in the *New England Journal of Medicine*, a correction may well need to be published as to Bérard (2015) in the *American Journal of Obstetrics & Gynecology* to alert the scientific and medical community of these errors and to guard against the possibility of medical decisions being based upon flawed data. The public health concerns presented in this litigation are too important to allow Plaintiffs to hide behind baseless confidentiality designations.

2. Documents Regarding the Now-Published Correction to Louik (2007)

Dr. Kimmel's supplemental expert report explains that, in reviewing the data from Louik (2007), he notices a potential error in the data for Zoloft and septal defects. Kimmel 7/2/15 Rpt. [1388-1] at 1. Dr. Kimmel thus contacts Dr. Mitchell, the senior author of Louik (2007), and asks a question about the data as reported. *Id.* at 7.

> I am writing to ask you a question about your 2007 NEJM paper on SSRIs and birth defects. By way of disclosure, I have been serving as a consultant in litigation surrounding [Zoloft] and birth defects.
>
> My question relates to the OR and CI for [Zoloft] and septal defects in Table 2 of the paper: 2.0 (1.2-4.0). When I plot this on a log scale, the CI is not symmetric. Also, the OR seems a bit high given the prevalence of exposure in the [Zoloft] group.
>
> Can you help me to clarify the results for [Zoloft] and septal defects so I am clear that I have the correct numbers?

Id. On July 1, 2015, Dr. Mitchell confirms that Dr. Kimmel is correct and that the reported confidence interval for the finding for Zoloft and septal defects is, in fact, wrong.

> As it happens, we were able to retrieve the original files for the paper, and ***we did indeed err in transcribing the CI for the adjusted odds ratio for [Zoloft] exposure in relation to septal defects*** (all of the other values in that table were correct). The point estimate (2.0) was correct, but ***the published CI of 1.2-4.0 should have been 1.0-4.0.*** We have notified the NEJM of the error, and they will publish a correction along with a corrected online version of the [manuscript] that reflects the change in CIs. Thanks for bringing this matter to our attention.

Id. at 6 (emphasis added).

Dr. Kimmel and Pfizer immediately disclose this information in a supplemental report served on July 2, 2015. On the day of the *Daubert* hearing, July 7, 2015, Dr. Jewell emails Dr. Mitchell about this issue, asking him for the "statistical analysis … that yielded this revised odds ratio estimate and confidence interval." Ex. 10 at 47. Dr. Mitchell replies on July 13, 2015, confirming that Dr. Kimmel correctly identified an error in the study.

> Dr. Kimmel brought to our attention a potential error is one of our confidence bounds that we published in the NEJM. There was indeed an error, and we have submitted a correction to the Journal. Our efforts were solely directed at assuring that what we published was correct; we are not involved in the litigation in any way and as a matter of policy we allow our publications to speak for themselves.

Id. at 47.

We now know that there was another email exchange with the Louik (2007) authors – not marked as confidential by Plaintiffs – about this subject. On July 8, 2015, Dr. Sander Greenland, a consulting expert for Plaintiffs, who was aware of the communications between Drs. Kimmel and Mitchell, emails other co-authors of Louik (2007), Drs. Martha Werler and Sonia Hernandez-Diaz. Hoping to find out that the "1.0" was actually greater than "1.0" – *e.g.*, 1.01 and, thus, statistically significant – Dr. Greenland asks them if they could provide the second digit past the decimal point for the corrected confidence interval (95% CI 1.0-4.0), which, as reported in the published study, went only to the first digit past the decimal point.

> Alan [Mitchell] supplied the defense expert with the correction showing 2.0 (1.0, 4.0). Unsurprisingly, the big question it has raised is what are the results to two digits past the decimal point, particularly what is the lower limit out to one more digit?
>
> Alan said in the e-mails to Kimmel that he would be consulting with his coauthors, so I am writing to ask if either of you can state the estimate in more detail?

Ex. 6 at 9.

Dr. Hernandez-Diaz replies to Dr. Greenland that "Carol Louik run the analyses and provided the estimates. I do not know the decimal points." *Id.* Dr. Hernandez-Diaz also refers

Dr. Greenland to the Centers for Disease and Control (CDC) study by Reefhuis et al. published that same day in the *British Medical Journal* "concluding there are no increased risks associated with [Zoloft]." *Id.*[4] Dr. Greenland then writes back, and launches a broad-based attack, now advancing the view that statistical significance is a "testing fetish."

> Statisticians and epidemiologists freely present opinions in these legal documents that pander to the testing fetish even though they wouldn't dare do that in one of our journals (and wouldn't even be allowed to in Epidemiology), and the Supreme Court itself has rejected that standard (see last attachment). Still, the judge in this case puts great stock in the magic 0.05 so I am copying this material to Carol [Louik].

Id. at 12. What Dr. Greenland – a co-author of Professor Kenneth Rothman's *Modern Epidemiology* (3d ed. 2008) – disparages as the "testing fetish" and the "magic 0.05" for statistical significance is, in fact, as this Court has repeatedly recognized, part of the reliable and generally accepted methodology in the fields of teratology and epidemiology. *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig. (Zoloft I)*, 26 F. Supp. 3d 449, 455 (E.D. Pa. 2014); *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig. (Zoloft III)*, 2015 WL 314149, at *2 (E.D. Pa. Jan. 23, 2015). This Court properly rejected reliance on the "Rothman approach" and Dr. Greenland's misguided view of the language in the Supreme Court's decision in *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309 (2011). *Zoloft III*, 2015 WL 314149, at *4.

This Court's decisions as to the importance of statistical significance find further support in the emails between the Louik (2007) study authors and the editors of the *New England Journal of Medicine*. In discussing what corrections needed to be made to Louik (2007), the NEJM editors decide that it was not enough for the study authors to simply correct the numbers in the confidence interval. Rather, the NEJM editors recognize that confidence intervals that include 1.0 are not – "per usual criteria" – statistically significant. Ex. 10 at 34. The NEJM editors therefore require the study authors to "remove emphasis on findings that did not meet 'formal' criteria for stat[istical] significance" in order to be published. *Id.* at 38-39.

[4] Reefhuis et al., *Specific SSRIs and birth defects: bayesian analysis to interpret new data in the context of previous reports*, BMJ 350:h3190, at 6 (Tbl. 3) (2015) [1460-1].

On July 13, 2015, Dr. Mitchell replies to Dr. Greenland's inquiry as to the corrections.

> [O]ur response to [Dr. Kimmel's] inquiry had nothing at all to do with his involvement in litigation …. The simple fact was that he raised a question about a CI we published, and ***on careful re-examination, we found that we had indeed erred. We submitted a correction to the NEJM***, and we provided the corrected information to Steve [Kimmel]. As is the case for any of our published work, we cannot control how that information is used, including in judicial proceedings.
>
> We let our publications speak for themselves and do not respond to the infinite number of questions that may be of interest to litigants and that might draw us into these legal proceedings.

Id. at 97-98 (emphasis added). In response, on July 14, 2015, Dr. Greenland states he is "surprised and deeply disturbed" by Dr. Mitchell's email. *Id.* at 109. He interprets Dr. Mitchell's email as "a personal slight" and accuses him of making "an ethical mistake."

> I am now surprised and deeply disturbed that you have refused my request, especially since Kimmel did not submit his request to everyone on the paper either, and I can see no labor, confidentiality, legal or embargo issue involved here to justify withholding this tiny bit of information. So your withholding the data seems to me to be a personal slight, as well as an ethical mistake as I will now explain.

Id. at 109-10. In stark contrast to Dr. Kimmel's email to Dr. Mitchell, which simply asked a clarification question, Dr. Greenland's email appears to be threatening Dr. Mitchell.

> You responded quickly to Steve Kimmel's inquiry even though his e-mail made clear it was litigation motivated. We all can see exactly how Steve Kimmel used the information - Please read the first page of the attached:, he used it precisely for the type of dichotomy abuse you say you decry, quoting your e-mail directly in his defense report. Thus it is your prompt aid to defense which created the need for my request, which was based on what may be seen as Kimmel's misrepresentation of facts which you supplied.
>
> In other words, my request is not a random one for some isolated case, but one produced by your own actions. Thus I find it difficult to comprehend how you can claim to distance yourself in this matter by denying information to a colleague after your aid to a litigant. And frankly, Allen, if the more precise result would not support his claim of nonsignificance, by refusing requests for this detail you are now abetting defense misrepresentation to the court of your actual results. In any event, the precise results may well become public along with the correspondence via subpoena, so I'm afraid you are already involved in this case, like it or not.

> I'd be happy to let our correspondence and the attached correspondence stand (along with the precise result when it becomes available) as a matter of public record for others to infer what principles you were applying and violating in denying my request.

Id. at 110-11. Then, after lodging these contentions with Dr. Mitchell, Dr. Greenland proposes what he pitches as "an amicable and constructive solution." Ex. 5 at 5. Dr. Greenland states that he is preparing an *amicus* brief for this Court that addresses the topic of statistical significance and he asks the Louik (2007) authors to join him on the *amicus* brief. Dr. Greenland includes a draft of the *amicus* brief in his email. Notwithstanding his lack of legal training, Dr. Greenland endeavors to present a legal analysis, yet one which this Court has previously addressed.

> The need to go beyond statistical significance when considering evidence has been affirmed by a rare unanimous opinion by the Supreme Court of the United States [Matrixx]. We strongly urge the court in the present case to study this decision in detail, and to modify its current application of significance criteria to apply only to overall evidence, not individual studies. Such a modification would bring the deliberations in this case into line with the Supreme Court opinion and also align with current recommendations in the peer-reviewed literature and leading textbooks on evidence synthesis [cites].

Id. at 6. After being fully briefed by counsel in this matter, this Court has already studied this decision in detail and rejected this misreading of *Matrixx*. As Dr. Mitchell subsequently notes, Dr. Greenland's July 14 email shows he "is acting as a lawyer, not a scientist." Ex. 10 at 108.

Dr. Hernandez-Diaz later declines Dr. Greenland's invitation to join his *amicus* brief. Ex. 5 at 2. In doing so, she makes clear that she "believe[s] that ***chance*** might have played a role in some of the initially reported associations" in Louik (2007). *Id* at 3. (emphasis added). She further explains that "other studies have ***not replicated*** the proposed association (I had in mind the recent BMJ Bayesian analysis by CDC)," Reefhuis (2015). *Id* at 2. (emphasis added).

Dr. Greenland was apparently fixated on obtaining the second digit past the decimal point for the confidence interval because if the lower bound of the confidence interval was slightly above 1.0 – *e.g.*, 1.01 – then that would allow Plaintiffs to argue that the confidence interval was actually "statistically significant." But we now know precisely the value of the lower bound of the confidence interval. It is less than 1.0 and was rounded-up to 1.0. Non-confidential

documents subpoenaed by Plaintiffs make clear that the lower bound of the confidence interval is ***0.982***. Ex. 10 at 51. As Dr. Louik states, "the lower bound is 0.982, which does round up to 1.0, and in my opinion, anyone who cares that much about the second decimal place doesn't really understand the nature of observational studies." *Id.* In sum, the Louik (2007) study authors have confirmed that the confidence interval includes 1.0 and that the lower bound is not even nominally above 1.0. *Id.* at 33.

Despite Plaintiffs' experts' efforts to undermine it, the correction to Louik (2007) has been published in both the online and print versions of the *New England Journal of Medicine*. Pfizer's Not. of Supp'l Exs. [1453-1], [1454-1], [1461-1]. The finding for Zoloft and septal defects in Louik (2007) is not statistically significant.

Documents produced by Dr. Mitchell reveal that Dr. Jewell also sought information on the corrected confidence interval from Dr. Mitchell. Ex. 10 at 47. Dr. Jewell did so for the same reason that Dr. Greenland did: to attempt to show that the lower bound was greater than 1.0 and, thus, statistically significant. It is not. There is no justification for Plaintiffs having [redacted] Other emails on the same topic (produced after August 1) are not designated as confidential. No explanation for the confidentiality of the former can be derived from their content. Nor is there any sound explanation for the disparate treatment, with the August 1 production designated as confidential in its entirety, but the subsequent productions – which cover several of the same subjects – not at all. Plaintiffs' August 1 confidentiality designations should be de-designated in their entirety.

3. Documents Regarding Dr. Jewell's Re-Analysis of Huybrechts (2014)

Pfizer's *Daubert* briefing explains that Dr. Kimmel identified a series of methodological errors in Dr. Jewell's *post hoc* reanalysis of Huybrechts (2014) that render it "flawed" and "invalid." Pfizer's Br. [1210-1] at 20-22; Pfizer's Reply [1314] at 12; Kimmel 3/27/15 Rpt. (Ex. 11) at 25-27. One flaw is that Dr. Jewell took it upon himself to redefine an exposed group as a "paused" group and improperly compared an exposed group with an exposed group. The proper

methodology is to compare an exposed group with an unexposed (or paused) group. Pfizer's Br. [1210-1] at 21; Kimmel 3/27/15 Rpt. (Ex. 11) at 25-27. Another methodological flaw is that Dr. Jewell's reanalysis "does not include the full adjustment for confounding that the Huybrechts study performs." Kimmel 3/27/15 Rpt. (Ex. 11) at 25-27; *see also* Pfizer's Br. [1210-1] at 20.

Plaintiffs' document production reveals that [redacted]

[redacted]

Dr. Kimmel's point that Dr. Jewell's *post hoc* reanalysis of Huybrechts (2014) is inferior to the published study and is methodologically unsound. Kimmel 3/27/15 Rpt. (Ex. 11) at 25-27.

I. THE COURT SHOULD ORDER PLAINTIFFS TO DE-DESIGNATE THE DOCUMENTS AS CONFIDENTIAL

Plaintiffs bear the burden of establishing and justifying their blanket confidentiality designations over their August 1, 2015, document production. The Protective Order entered by this Court provides that "[t]he party designating information, documents, materials or items as Confidential Information bears the burden of establishing confidentiality." PTO 8 ¶ 8. "With respect to any motions relating to the confidentiality of documents or related information, the burden of justifying the designation shall lie with the designating party." *Id.* Plaintiffs must thus show "good cause … that disclosure will result in a clearly defined, specific and serious injury." *Shingara v. Skiles*, 420 F.3d 301, 306 (3d Cir. 2005). "[B]road allegations of harm are not sufficient to establish good cause." *Id.* Plaintiffs cannot meet their burden.

The documents at issue do not reveal any "individually identifiable health information" under HIPAA. Nor do they reveal "Plaintiff's personal identifying information, financial information, and medical/insurance information." PTO 8 ¶ 1. Thus, the information does not "violate any privacy interests." *Shingara*, 420 F.3d at 306 (citations omitted). Moreover, the information is not merely "important to the public," but is also "important to public health and safety." *Id.* The documents concern Plaintiffs' communications with authors of published, peer-reviewed medical and scientific studies. There is no legitimate and legally cognizable basis for Plaintiffs' confidentiality designations. The Court should order Plaintiffs to de-designate the documents produced on August 1, 2015.

CONCLUSION

For the foregoing reasons, this Court should grant the within motion.

DATED: New York, New York
August 17, 2015

QUINN EMANUEL URQUHART &
SULLIVAN, LLP

By : */s/ Mark S. Cheffo*
Mark S. Cheffo
Sheila L. Birnbaum
Bert L. Wolff
Katherine A. Armstrong
Jonathan S. Tam

51 Madison Avenue, 22nd Floor
New York, New York 10010-1601
(212) 849-7000

KAYE SCHOLER LLP
Pamela J. Yates
Bert L. Slonim
Aaron H. Levine
250 W. 55th Street, 4th Floor
New York, New York 10019-7649
(212) 836-8000

WHEELER TRIGG O'DONNELL LLP
James E. Hooper, Jr.
Andrew H. Myers
370 Seventeenth Street, Suite 4500
Denver, Colorado 80202-5647
(303) 244-1800

DECHERT LLP
Robert C. Heim
Judy L. Leone
2929 Arch Street
Philadelphia, Pennsylvania 19104-2808
(215) 994-4000

Attorneys for Defendants Pfizer Inc., including its former division J.B. Roerig & Co., Pfizer International LLC, and Greenstone LLC

CERTIFICATE OF SERVICE

I hereby certify that on August 17, 2015, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which sends electronic notification of such filing to all CM/ECF participants. An unredacted version of the foregoing is being lodged with the chambers of the Honorable Cynthia M. Rufe contemporaneously with this filing and has also been served via First Class U.S. Mail upon Mark P. Robinson, Jr. and Dianne Nast of the Plaintiffs' Steering Committee.

Dated: New York, New York
August 17, 2015

/s/ *Mark S. Cheffo*
Mark S. Cheffo